

Claims:

1. A pharmaceutical dosage unit comprising tibolone, in an amount of from 0.1 to 10 % by weight, and a pharmaceutically acceptable carrier, the carrier containing a water-insoluble starch product, characterised in that the starch content in the carrier is more than 10 % by weight.
5
2. A dosage unit according to claim 1, characterised in that the starch content in the carrier is at least 40 % by weight.
10
3. A dosage unit according to claim 2, characterised in that the starch content in the carrier is at least 50 % by weight.
4. A dosage unit according to claim 3, characterised in that the starch content in the carrier is 90 - 100 % by weight.
15
5. A dosage unit according to any one of the preceding claims, characterised in that the starch product is selected from the group consisting of Starch 1500, potato starch, corn starch, wheat starch, and mixtures thereof, the group including modified starches, agglomerated starches, and granulated starches.
20
6. A dosage unit according to any one of the preceding claims, characterised in that the tibolone is present in an amount of 2 % by weight or less.
- 25 7. A dosage unit according to claim 6, characterised in that the quotient of the weight percentage of the tibolone medicinal agent in the dosage unit and the weight percentage of the starch product in the carrier is at most 0.02.
8. A dosage unit according to claim 7, characterised in that said quotient is at most 0.01.
30
9. A dosage unit according to any one of the preceding claims, characterised in that it contains up to 5% by weight of a stabiliser selected from the group consisting of antioxidants, chelating agents, and mixtures thereof.

10. A dosage unit according to claim 9, characterised in that the stabiliser is selected from the group consisting of ascorbyl palmitate, ascorbyl stearate, sodium ascorbate, and mixtures thereof.

5

11. A method of making a dosage unit according to any one of the preceding claims, the method comprising the steps of providing a carrier of the desired composition, mixing tibolone, and optionally stabilising agents, with a portion of the eventually needed amount of carrier to obtain a pre-mix, screening the pre-mix, further mixing it with the remaining portion of the carrier, and finally admixing with lubricant.

10

12. The use of a starch product as a carrier for pharmaceutical dosage units comprising tibolone for the purpose of increasing the stability of the tibolone.